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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,694	01/24/2002	Stephane Gobron	CLJV-31795A	1035

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EXAMINER	
MAYES, MELVIN C	

ART UNIT	PAPER NUMBER
1791	

MAIL DATE	DELIVERY MODE
02/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/056,694	GOBRON ET AL.	
	Examiner	Art Unit	
	Melvin C. Mayes	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9 and 48-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-9 and 48-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

(1)

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(2)

Claims 1, 3, 9 and 48-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 131 277 in view of Yang et al. 6,042,754 and Martin et al. 5,649,410.

EP 0 131 227 (EP '227) discloses a method of making a contact lens comprising: extruding a film of thermoplastic processable material; punching a blank from the film; molding the blank between two molding dies (first and second mold parts) at a temperature higher than the glass transition point of the thermoplastic material by 20-80°C but lower then the melt flow temperature thereof (thus between 120°C below glass transition temperature and the degradation temperature) at a pressure of 10-100 kg/cm^2 to for the contact lens. EP '227 discloses hydrating the contact lens and discloses that the thermoplastic material can be selected from: cellulose ester, homopolymer or copolymer of methacrylate ester, acrylate ester, styrene, acrylonitrile and vinyl chloride; polycarbonate, polyamide or a polymer blend of these (which includes polymers which are hydrophilic, form a hydrogel when hydrated or contain latent crosslinking groups) (see also corresponding document JP 60-49906). EP discloses that the film preferably has a thickness of 0.1 to 1.0 mm, discloses that the weight of the punched blank slab results from its diameter and film thickness and discloses that a contact lens has a weight of about 15 to 30 mg. EP '227 provides an example of punching a blank of diameter of 9 mm from a film 0.3 mm thick to form

a blank of 18.3 mg weight (translation, pgs. 2-11). EP '227 does not specifically disclose providing the molding dies (mold parts) with clearance such that gas escapes from the mold cavity but none of the thermoplastic material (polymer) escapes or disclose packaging the contact lens.

Yang et al. 6,042,754 teaches that in molding ophthalmic lenses using upper and lower dies, the die set can be provided such that only air is vented out and all of the material is kept inside of the die set (col. 11, lines 49-52).

Martin et al. teach that the manufacturing assembly line for contact lenses includes molding, hydrating and inserting into packaging elements (col. 2, lines 5-67).

It would have been obvious to one of ordinary skill in the art to have modified the method of EP '277 for making a contact lens by providing the two molding dies with clearance such that gas escapes from the mold cavity but none of the thermoplastic material (polymer) escapes, as taught by Yang et al. for making an ophthalmic lens using a pair of dies.

It would have been obvious to one of ordinary skill in the art to further modified the method of EP '227 by packaging the hydrated contact lens as Martin et al. teach that the manufacturing assembly line for contact lenses includes molding, hydrating and inserting into packaging elements.

Regarding providing the pellet (blank) as having a length (L) to diameter (D) ratio L/D between 0.2 and 5, the ratio of length (corresponds to thickness of the blank) to diameter of the punched blank would obviously depend on the thickness of the film from which the blank is to be punched and the desired weight of the blank (which corresponds to volume of the blank). EP '227 discloses an example of punching a blank of diameter of 9 mm from a 0.3 mm thick film

to form a blank of 18.3 mg weight. This blank has a volume of about 19 cubic mm. To form a blank of the same weight and volume using a film of thickness of 1.0 mm instead of 0.3 mm would require punching a blank of diameter of about 4.9 mm. This provides a L/D ratio, 1/4.9, of about 0.2, which is encompassed by the claimed range of "between 0.2 and 5."

While EP '227 discloses that the film from which the blanks are punched "preferably have a thickness of 0.1 to 1.0 mm," one of ordinary skill in the art would have recognized that weight of the contact lens (15 to 30 mg) corresponds to volume of the blank, which is based upon the thickness (length) and diameter of the blank. One of ordinary skill in the art would have recognized that to achieve a desired blank volume and contact lens weight, as the thickness of the film varies, so must the diameter of blank to be punched vary, which results in varying L/D ratios of the punched blanks. While ratio of 0.2 to 5 has been set forth by Applicant as preferable for a pellet, Applicant has set forth a broad ratio range of 0.1 to 10.0 and has not forth any evidence that the range of 0.2 to 5 provides any improved or unexpected results over the broad range of 0.1 to 10.0.

(3)

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 131 277 in view of Yang et al. 6,042,754 and Martin et al. 5,649,410 as applied to claim 1, and further in view of either Ruhlin 5,100,590 or Lee 4,619,793.

Ruhlin teaches that in addition to cutting a blank for an ophthalmic lens from a plate for molding, a blank can be cut from a rod (col. 2, lines 34-36).

Lee teaches that a lens blank for making a contact lens can be cut from a suitable rod, punched or stamped from a sheet or cast from molds (col. 9, lines 24-29).

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by cutting the blank from an extruded rod (wire) instead of from an extruded film, as taught by either Ruhlin or Lee, as alternatives for providing a blank for making an ophthalmic or contact lens. Punching a blank from a film or cutting a blank from a wire to form a blank of the desired weight for a contact lens would have been obvious to one of ordinary skill in the art as alternatives for providing a blank for forming a contact lens. It would have been obvious to one of ordinary skill in the art to substitute the use of a rod for a film to achieve the predictable result of providing a substrate from which blanks can be cut for making a contact lens by molding. As with the use of a film, one of ordinary skill in the art would have recognized that to achieve a desired blank volume and contact lens weight from a rod, as the diameter of the rod varies, so must the length of blank to be punched vary, which results in varying L/D ratios of the punched blanks. While ratio of 0.2 to 5 has been set forth by Applicant as preferable for a pellet, Applicant has set forth a broad ratio range of 0.1 to 10.0 and has not forth any evidence that the range of 0.2 to 5 provides any improved or unexpected results over the broad range of 0.1 to 10.0.

(4)

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 131 277 in view of Yang et al. 6,042,754, Martin et al. 5,649,410 and either Ruhlin 5,100,590 or Lee 4,619,793 as applied to claim 4, and further in view of Ingram 5,456,587.

Ingram teaches that a plastic pellet delivery system for automatic placement of a pellet in a mold for molding is provided by moving a knife to engage the extrudate from the nozzle of the

extruder, cutting a pellet from the extrudate, moving the knife toward the mold and using plungers to deflect the pellet toward the mold (col. 1-3).

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by providing the blank from an extruded rod (wire) to the mold by providing a knife which cuts the blank from the extrudate from the extruder, moving the knife to the mold and using plungers (ejector pins) to deflect the blank to the mold, as taught by Ingram as used to deliver a plastic pellet from an extruder to a mold. One of ordinary skill in the art would have known to combine the known plastic pellet delivery system of Ingram with the method of the references as combined for molding a contact lens with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

(5)

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 131 277 in view of Yang et al. 6,042,754 and Martin et al. 5,649,410 as applied to claim 1, and further in view of Yamanaka et al. 6,099,765.

Yamanaka et al. teach that funnel-shaped holding pad formed of silicon rubber and connected to a vacuum source for holding optical material to the holding pad is used to hold optical material when moving it into and away from the mold apparatus (col. 4, lines 17-25).

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by using a silicon rubber pad and vacuum to separate the contact lens from the dies, as taught by Yamanaka et al., as known for use to hold optical material when moving it away from the mold apparatus. One of ordinary skill in the art would

have known to combine the known method of moving optical material as taught by Yamanaka et al. with the method of the references as combined for molding a contact lens with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Response to Arguments

(6)

Applicant's arguments filed November 2, 2007 have been fully considered but they are not persuasive.

Applicant argues that the EP '277 reference does not suggest a motivation to combine the references but teaches away from the combination. Applicant argues that in EP '277 the film (blank) is the exact weight needed for the final product thus no suggestion to combine with Yang to achieve the claimed variable volume between first volume and second volume such that gas escapes and none of the polymer escapes. Applicant argues that EP '277 teaches a L/D ratio of 0.017-0.044 and teaches away from the claimed L/D ratio of between 0.2 and 5.

(7)

EP '227 does disclose that it is advantageous for the quality of the molded element if the blank already has the precise weight of the desired molded element (pg. 7, lines 7-10). However, Yang also teaches that the material to be molded can be the exact amount needed for making the article, and in that case, the die set is provided such that only air is vented out and all of the material is kept inside of the die set (col. 11, lines 49-52). The motivation for combining the references is thus found in Yang which suggests that the two molding dies of EP '277 should

have a clearance such that gas escapes from the mold cavity but none of the thermoplastic material escapes during molding which is used when the material to be molded is of the exact amount for the lens. As to the claimed "variable volume between first and second volume…" molding a blank between molding dies to reshape the blank to form a lens necessarily provides variable volume of a mold cavity between first and second volumes, because as the mold dies close too reshape the blank the volume in the mold cavity changes from an initial volume to a final small volume which is the final shape of the lens.

As to EP '277 and the claimed L/D ratio, the reference is not so limited. EP '277 discloses that the film preferably has a thickness of 0.1 to 1.0 mm, with the thickness range of 0.15-0.4 mm being only especially preferred. Applicant has taken the especially preferred thickness range of 0.15-0.4 mm and the one disclosed diameter of 9 mm to come up with an L/D ratio range of 0.017-0.044. However, EP '277 discloses that the film can have thickness of 0.1 to 1.0 mm, that the weight of the punched blank slab results from its diameter and film thickness and that a contact lens has a weight of about 15 to 30 mg, and in the example, the blank has a weight of 18.3 mg and volume of about 19 cubic mm. Based on this disclosure, one of ordinary skill in the art would have recognized that to achieve a desired blank volume and contact lens weight, if the thickness of the film varies, so must the diameter of blank to be punched also vary to achieve the same blank volume and lens weight, which results in varying L/D ratios of the punched blanks. So for example, to form a blank of the same weight and volume as the example but using a film of thickness of 1.0 mm (which is in the preferred thickness range) instead of thickness of 0.3 mm would require the blank to have a diameter of about 4.9 mm. This results in an L/D ratio, of about 0.2, which is encompassed by the claimed range of "between 0.2 and 5."

While L/D ratio of 0.2 to 5 has been set forth by Applicant as preferable for a pellet, Applicant has set forth a broad L/D ratio range of 0.1 to 10.0 and has not forth any evidence that the more limited ratio range of 0.2 to 5 provides any improved or unexpected results over the broad range of 0.1 to 10.0.

Conclusion

(8)

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melvin C. Mayes whose telephone number is 571-272-1234. The examiner can normally be reached on Mon-Fri 7:30 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Phillip C. Tucker can be reached on 571-272-1095. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melvin C. Mayes
Primary Examiner
Art Unit 1791

MCM
January 31, 2008

/Melvin C. Mayes/
Primary Examiner, Art Unit 1791